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AUG 2 2005

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MORGAN, LEWIS & BOCKIUS L.L.P.
2 Palo Alto Square
3000 El Camino Real, Suite 700
Palo Alto, California 94306

In re Application of
Shiau et al
Serial No. : 09/830,693
Filed : March 30, 1999
Attorney Ref No. : 61040-0013

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on March 9, 2005, to request the review of the restriction requirement. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed on April 27 2001 as a national stage application of PCT/US99/06937 filed on 30 March 1999. On 10/23/2003 applicants amended the original 71 claims and added new claims 72-141.

A lack of unity determination was mailed to applicants on 6/25/2004. In this paper the examiner divided the 141 claims into ten different groups.

On 8/19/2004, applicants elected with traverse Group 5, claims 44-48, drawn to a cocrystal comprising a portion of the estrogen receptor.

In response to the election, the examiner acknowledged the election of Group 5, claims 44-48 and further considered the traversal and found applicants' arguments non-persuasive and issued a new lack of unity determination in which elected group 5, contained claims 44-48, 50 and 136-138 and 142-148 and made the lack of unity determination FINAL, in the paper of 12/9/2004. The groups were as follows:

Group I, claims 1-25, 72-133, and 140-141, drawn to methods of identifying compounds which modulates nuclear receptor activity or modulates binding of a ligand to a nuclear receptor, classified in class 703, subclass.

Group II, claims 29-33, 67-71 and 134-135 drawn to a method of modulating nuclear

receptor activity in a mammal, classified in class 424, subclass 198.1. This Group is subject to election of species, as set forth below.

Group III, claims 34-35 and 39, drawn to a machine readable storage medium capable of graphical three-dimensional representation, classified in class 702, subclass 27.

Group IV, claims 40-43, drawn to a machine readable storage medium comprising a program for correspondence of data, classified in class 708, subclass 403.

Group V, claims 44-48, 50, 136-138 and 142-148, drawn to a crystal comprising a portion of an estrogen receptor and an agonist, classified in class 350, subclass 399.

Group VI, claims 49 and 51, drawn to a crystal comprising a portion of an estrogen receptor and an antagonist, classified in class 350, subclass 399.

Group VII, claim 139, drawn to a crystal comprising a portion of an estrogen receptor and an antagonist, classified in class 350, subclass 399.

Group VIII, claims 52-66, drawn to a computational method of designing a nuclear receptor ligand, classified in class 703, subclass 12.

A first office action on the merits was also mailed as a part of this same communication, in which claims 48, 50 and 136-138 and 142-148 were rejected under 35 USC 112 1st and 2nd paragraphs, and claims 136 and 137 were rejected under 35 USC 102(e).

In response to the non-final rejection of 12/9/2004, applicants responded with the instant petition, accompanying arguments and amendments of the claims on 3/9/2005.

DISCUSSION

The application, file history and petition under 37 C.F.R. 1.144, to request review of the lack of unity determination has been considered.

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on March 9, 2005, to request: 1) the joinder of Groups V and VII and 2) joinder of claims 1-25, 29-35, 39, 52-133 and 140-141 from Groups I, II, III, (VII) and VIII into a single group, at such time as any of groups I, II, III, (VII) and VIII is elected for further prosecution.

With respect to issue 1), applicants submit that Groups V and VII share a special technical feature of the estrogen receptor ligand binding domain; an agonist bound to the ligand binding domain and a molecule bound to the coactivator binding site and that the claims of groups V and VII satisfy the unity of invention standard and request rejoinder thereof.

Applicants' argument with respect to the claims of groups V and VII are found

persuasive.

With respect to issue 2) joinder of claims 1-25, 29-35, 39, 52-133 and 140-141 from Groups I, II, III, (VII) and VIII into a single group, applicants submit that according to the Examiner's own identification of a "special technical feature" in the claims of Groups I, III and VIII, at least claims 29-33 and 67-71 of Group II should properly be examined with one of groups I, III or VIII.

Applicants' complete argument has been considered, however found non-persuasive. Applicants' submission that at least claims 29-33 and 67-71 of Group II should properly be examined with one of groups I, III or VIII on the basis of the identification of a "special technical feature" is not persuasive.

Applicants additionally believe that the grounds for separating the claims of Groups I, II, III and VII are improper according to practice under PCT Rules 13.1 and 13.2.

Alternatively, applicants submit that all claims in Groups I, II, III and VIII, except claims 134 and 135 possess the following special technical features and accordingly should be joined into a single group:

An atomic structural model of the estrogen receptor ligand binding domain, comprising atomic coordinates of: helix 12 of the ligand binding domain; a coactivator binding site and a coactivator bound to the coactivator binding site

Applicants' complete argument concerning Groups I, II, III and VIII has been considered, however, is found moot given that only a single national phase application may be filed under 35 USC 371 as a result of each international application. As applicants have elected Group V in the instant application, any subsequent divisional applications would be filed under 35 USC 111(a) and would be subject to U.S. restriction practice rather than PCT unity of invention practice.

Further, applicants' arguments regarding rejoinder of Groups I, II, III and VIII are non-persuasive. If applicants had elected one of groups I, II, III or VIII and traversed the lack of unity determination, the traversal would have been non-persuasive based upon the following.

Group I is drawn to a method of identifying compounds which modulate nuclear receptor activity or binding. Group II is drawn to a method of modulating nuclear receptor activity. Group III is drawn to a machine readable storage device capable of graphical three-dimensional representation. Group VIII is drawn to a computational method of designing a nuclear receptor ligand. Groups I, II and VIII are each drawn to different methods requiring different steps and Group III is drawn to a machine readable storage device not required to be made by or required to be used in any of the methods of Groups I, II or VIII. The method of Group I requires an active step of screening test compounds in a binding assay which is not required for groups II or VIII. The method of Group II requires an active step of administering to a mammal a compound, which is not required for Groups III or VIII. The method of Group VIII requires an active step of carrying out a chemical modification of a chemical moiety, which is not required for Groups I

or II. This each method of Groups I, II and VIII comprise different active steps and are thus different methods.

This application was filed as subject to 35 U.S.C. § 371 (see MPEP § 1895.01). Unity of invention as provided for by 37 C.F.R. 1.475 must be present, as cited below:

Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

A product and a process specially adapted for the manufacture of said product; or

A product and a process of use of said product; or

A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

A process and an apparatus or means specifically designed for carrying out the said process; or

A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph b of this section, unity of invention might not be present.

If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As stated above, a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to only one of the listed combinations of categories and if multiple products, process of making or using are claimed, the first invention of the a category first mentioned in the claims and the first recited inventions of each of the other categories related thereto will be considered as the main invention in the claims. This each of Groups I, II and VIII are drawn to different method that do not share unity of invention and are not linked as a main invention.

DECISION

For these reasons, the petition under 37 C.F.R. 1.144 to request is **GRANTED-IN-PART**.

The request for the joinder of Groups V and VII is **GRANTED**.

The request for (2) joinder of claims 1-25, 29-35, 39, 52-133 and 140-141 from groups I, II, III (VII) and VIII into a single groups at such time as any of groups I, II, III and VIII is elected for further prosecution is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to take appropriate action as a result of this petition decision and to consider the amendments and arguments filed by applicants on 3/9/2005.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.



Bruce Kisliuk
Director, Technology Center 1600